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PACKAGING FOR THE INDIVIDUAL PRESENTATION OF AT LEAST ONE SCREW

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The invention relates to a package for individually presenting at least one screw comprising a shank and a head, in particular an osteosynthesis screw.

The present invention also relates to providing a packaging and presentation assembly for osteosynthesis equipment and including a package of the above-mentioned type.

The present invention also relates to a protective assembly including an assembly of the above-mentioned type for packaging and presenting osteosynthesis equipment.

Screws and plates for osteosynthesis are used for reducing bone fractures, i.e. for putting two bone fragments back into position relative to each other and for holding them in position.

Such osteosynthesis screws and plates are conventionally used in maxillofacial surgery, whether for repair purposes in order to reduce an accident or fracture, or for functional and/or esthetic purposes as in the event of mandibular and maxillary osteotomies.

When performing such surgery, the surgeon has a set of plates and a set of fastener screws that have been made available by being taken out of their respective packages (e.g. one receptacle containing plates and another receptacle containing fastener screws) prior to being sterilized and then placed on a tray where they remain accessible throughout the surgery.

Depending on the type of surgery to be performed, the set of plates may comprise one or more plates that may be identical or different, and the set of screws may comprise one or more screws that are identical or different. These sets are generally constituted by more than a single piece since even when only one piece is required for the surgery, it is necessary to have at least one other piece available as a spare in the event

that the first piece to be handled should be accidentally damaged or should be found to be in an aseptic state that is no longer satisfactory.

In addition, even when the type of plate and the type of screw for use is determined beforehand, uncertainty can remain as to the dimensions that are best adapted to the patient's morphology, particularly in terms of the length of screw to be used.

Consequently, a large amount of manipulation is necessary before, during, and after surgery concerning these elements (plates and screws) constituting a set of equipment for osteosynthesis:

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before surgery: theater personnel must prepare the items constituting the set of osteosynthesis equipment, i.e. they must know which type(s) of screws and plates are to be provided, and the numbers thereof, take them from stock, and then sterilize them and put them into sealed envelopes; thereafter these items wait until shortly before surgery, at which time the sealed envelopes are opened and the items are placed on the above-mentioned tray;

· during surgery: some or all of the items constituting the set of osteosynthesis equipment are taken using forceps or some other appropriate instrument prior to being put into place and secured to the patient using instruments provided for this purpose; the go-and-return trips of the forceps (or other instrument) between the tray and the patient (or the above-mentioned instrument) leads to risks of dirtying and contamination of items that have not yet been used and that remain on the tray; and

· after surgery: from the above, it can be seen that, prior to being put back into stock ready to be taken for some future operation, any remaining items that have not been damaged mechanically will need to be subjected to a new cleaning and sterilization procedure regardless of whether or not they have been touched by an

instrument; the important point is that remaining items are no longer sterile.

An object of the present invention is to solve the above-mentioned problems so as to reduce the amount of handling that needs to be performed in theater, including in association with sterilization, so as to provide a surgeon with a set of osteosynthesis equipment that can be used directly in theater, while guaranteeing the osteosynthesis equipment in terms of quality and sterility.

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To this end, in a first aspect, the present invention provides a package that comprises a tube suitable for being held in the hand and presenting a first end and a second end, said tube being provided with at least one housing for receiving said screw in unitary manner, said housing presenting an opening into said first end, and closure means closing said housing in sealed manner and suitable for being opened, said housing extending in a longitudinal direction and presenting a first portion for receiving said shank of the screw and a second portion, said second portion being larger than the first portion and being suitable for receiving said head of the screw pressed thereagainst, said second end serving as a stand suitable for pressing against a substantially horizontal plane, in particular in order to give access to the screw situated in said housing via said opening when said closure means are open, with said stand extending perpendicularly to said longitudinal direction.

It will thus be understood that because of the presence of the housing in the tube, the screw is placed in a location that is sterilizable, and that also provides direct access for the tip of the screwdriver blade once the closure means have been opened.

More precisely, such a package enables the surgeon to take hold of the screw easily and directly, with the surgeon holding the tube firmly in one hand while the

tube is standing on its base, and using the other hand to bring the tip of the screwdriver blade into the socket situated in the head of the screw, the tip staying in place because the head of the screw is pressed against the second portion of the housing, with the reaction against the pressure force exerted by the tip coming from the second portion of the housing.

Overall, because of the arrangement of the present invention, it is possible simultaneously to package and to protect sterile osteosynthesis equipment, and also to present it so that it can be engaged directly by the tool, i.e. the screwdriver, without requiring any prior handling other than opening the closure means closing the opening to the housing in the tube. In particular, it is not necessary to extract the screw from the tube before taking hold of it, thereby reducing the amount of manipulation that needs to be performed, and thus reducing the risks of contamination prior to the screw being put into place by the surgeon.

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In a second aspect, the present invention also provides a packaging and presentation assembly for a set of osteosynthesis equipment comprising one or more items that are identical or different, that are of the same or different natures, and that include at least one osteosynthesis screw housed in a package of the above-specified type in accordance with the first aspect of the invention.

In particular, in this second aspect, it is sought to obtain an assembly in which it can be guaranteed visually that use is first use since a set of osteosynthesis equipment was sterilized.

In a first embodiment of the second aspect, there is provided an assembly for individually packaging and presenting a series of screws each comprising a shank and a head, in particular osteosynthesis screws, the assembly being characterized in that it comprises at least two packages of the above-specified type in accordance with

the first aspect of the invention, each containing a said screw in its housing, and in that it further comprises an envelope enabling said packages to be interconnected by holding them one by one in sealed manner to form a string.

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Such an arrangement enables a set of osteosynthesis screws to be kept together while taking only the screw(s) needed during surgery, with the screws being taken one by one from each compartment of the envelope.

In a second embodiment of the second aspect, there is provided an assembly for individually packaging and presenting a screw comprising a shank and a head, in particular an osteosynthesis screw, the assembly being characterized in that it comprises a protective and packaging case surrounding a package of the above-specified type in accordance with the first aspect of the invention and containing said screw in the housing.

In a third embodiment of the second aspect, the invention provides an assembly for packaging and presenting a set of osteosynthesis equipment, said set of osteosynthesis equipment comprising at least one osteosynthesis screw and at least one plate, the assembly being characterized in that it comprises at least one dish, and a heat-sealable film closing said dish and cooperating therewith to define a storage space, said plate being placed in said storage space, the assembly further comprising a package of the above-specified type in accordance with the first aspect of the invention containing said screw in the housing, said package being disposed in said storage space.

In a fourth embodiment of the second aspect, the invention provides an assembly for packaging and presenting a set of osteosynthesis equipment, said set of osteosynthesis equipment comprising at least one osteosynthesis screw and at least one plate, the assembly being characterized in that it comprises a rigid support defining a plurality of storage compartments including at

least one storage compartment of a first type having a package of the above-specified type in accordance with the first aspect of the invention inserted therein and containing said screw, and at least one storage compartment of a second type for receiving at least one osteosynthesis plate.

In a variant of the fourth embodiment of the second aspect, said rigid portion forms a bottom portion, and the assembly further includes a lid portion, said lid portion being suitable for co-operating in reversible manner with said bottom portion between an open position and a closed position, and in said closed position, said lid portion is suitable for holding said package in said storage compartment of the first type and said osteosynthesis plate in said storage compartment of the second type.

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Each of these various embodiments serves to provide a packaging and presentation assembly containing a sterile set of osteosynthesis equipment of a variety of kinds, and/or providing different modes of presentation.

Furthermore, in a variant of the first and fourth embodiments of the second aspect, provision is made for the packaging and presentation assembly further to include an identification medium carrying visual information associated with said set of osteosynthesis equipment, said visual information comprising a bar code.

This advantageous disposition provides traceability of the set of osteosynthesis equipment contained in the packaging and presentation assembly, i.e. enables its history to be followed up. In the information that appears on the identification medium, either in the form of a bar code or in the form of a written description or in the form of drawings, or in several forms simultaneously, there can appear the nature of the material from which the equipment is made, the dimensions of the equipment, a serial or batch number in order to identify its origin, its date of sterilization, together

with the type of decontamination and sterilization means used (oven, gamma rays, ...), and also a recommended useby date, for example.

By way of example, such an identification medium can be constituted by one or more labels each carrying all or some of this information, these labels possibly being suitable for peeling off and sticking onto something else, e.g. the file relating to the patient who is going to receive the osteosynthesis equipment contained in said packaging and presentation assembly, or on whom said equipment is going to be used.

This identification medium is advantageously positioned directly on each package of the type constituting the first aspect of the present invention, i.e. on the tube.

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The identification medium may be placed both on the tube packaging the screw and on another element forming part of the packaging and presentation assembly constituting the second aspect of the invention.

Furthermore, in a third aspect of the present invention, there is provided a protection assembly characterized in that it comprises a packaging and presentation assembly of the above-specified type in accordance with the second aspect of the invention, a protective dish forming a container for said packaging and presentation assembly, and a heat-sealable film suitable for being removed by hand and closing said dish in sealed manner. This provides reinforced protection for the set of osteosynthesis equipment against the various stresses to which it can be subjected prior to being used.

Other advantages and characteristics of the present invention appear on reading the following description of a plurality of embodiments of the invention given by way of example and with reference to the accompanying drawings, in which:

- · Figure 1 is an exploded perspective view of a first variant of a package constituting a first aspect of the present invention;
- Figure 2 is an exploded perspective view of a second variant of a package in accordance with the first aspect of the present invention;
 - Figure 2A is a longitudinal section of the package shown in Figure 2;
- Figure 3 is a fragmentary perspective view of a third variant of the Figure 1 package in accordance with the first aspect of the present invention;
 - \cdot Figure 3A is a fragmentary longitudinal section of the package portion shown in Figure 3;
- Figures 4A and 4B are longitudinal section views
 of two alternatives of a fourth variant package in accordance with the first aspect of the present invention;
 - Figure 5 shows a first step of the Figure 4 package in use;
- 20 Figure 6 shows a second step of the Figure 4 package in use;

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- Figure 7 is a diagram of a first embodiment of the packaging and presentation assembly constituting the second aspect of the present invention;
- Figure 8 is a diagram showing a second embodiment of a packaging and presentation assembly constituting the second aspect of the present invention;
 - Figure 9 shows a third embodiment of a packaging and presentation assembly constituting the second aspect of the present invention;
 - · Figures 10 to 13 are perspective views showing several variants of a fourth embodiment of the packaging and presentation assembly constituting the second aspect of the present invention;
- Figure 14 is an exploded perspective view of a protective assembly constituting the third aspect of the present invention and comprising a protective dish and a

packaging and presentation assembly constituting the second aspect of the present invention; and

· Figure 15 is a perspective view from above and from one of its corners showing a variant protective assembly constituting the third aspect of the present invention and presenting a protective case shown in its open position and containing the dish of Figure 14.

Figure 1 is an exploded view showing a first variant of the first aspect of the present invention in the form of a package 100 comprising a tube 102, a stopper 104, and a screw 110.

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The tube 102 is shown as being a circular-section cylinder, but naturally the tube need not necessarily be cylindrical, and could have a section of any other suitable shape providing the tube can easily be held between the thumb and the index finger of the same hand. The tube 102 extends between a first end 102a (at the top of Figure 1) and a second end 102b (at the bottom of Figure 1). The second end 102b is defined by a plane face extending orthogonally to the main direction of the tube 102, and this plane face can act as a stand when the tube is stood upright on a surface that is substantially A housing 106 (see top of Figure 2A) opens out into the first end 102a in an opening 106a. This housing 106 presents circular symmetry. The housing comprises a first portion 106b tapering down to a bottom of the housing and serving to received the threaded shank of the screw 110, it being possible for this first portion to have some other shape, for example it could be cylindrical.

This first portion 106b is extended towards the opening 106a by a second portion 106c of larger section for receiving the head of the screw 110, and this second portion is shown as being in the form of a circular-section cylinder. This second portion 106c could equally well be in the form of a truncated cone, tapering towards the first portion at a relatively small angle (5° to 45°)

relative to the vertical (the main direction of the tube 102). Having a second portion 106b in the form of a truncated cone provides a sloping wall that makes it easier to center the blade of a screwdriver towards the center of the head of the screw, i.e. towards the axis of the tube 102.

This second portion 106c is extended towards the opening 106a by a third portion 106d that is larger and that serves to receive sealed closure means constituted by a stopper 104. In Figure 1, the third portion 106d is in the form of a circular-section cylinder.

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In particular, between said second portion 106c and said first portion 106b, there is provided a shoulder 106e having a substantially plane bearing face 106f facing towards said opening 106a, said head of the screw coming to bear against said substantially plane bearing face 106f. In Figures 1, 2, and 2A, the bearing face 106f is perpendicular to the longitudinal direction of the housing 106, i.e. it is horizontal when the tube 102 is standing on end. Other shapes are possible for this bearing shape 106f providing it is suitable for receiving the face of the screw head that faces towards the screw shank. In particular, this bearing face 106f is selected to have a shape that is complementary to the shape of the face of the screw head that faces towards the screw shank, in particular a shape that is frustoconical.

The concept of sealing, as applied to the portion of the stopper 104 that co-operates tightly with the inside face of the third portion 106d of the housing 106, is defined as constituting a barrier against penetration by a fluid, whether a gas or a liquid. Such sealing is broken on the first occasion that the stopper 104 constituting the closure means is opened, which means that it can no longer be guaranteed that sterility is maintained inside the housing 106.

It will thus be understood that said closure means comprise a stopper 104 and that said housing 106 presents

a third portion 106d that is larger than the adjacent second portion 106c, said third portion 106d being suitable for receiving said stopper 104 tightly so as to enable said housing 106 to be reclosed in reversible manner.

The tube 102 is preferably a cylinder of crosssection that is at least partially circular, so as to
make it easier to grasp between its first and second ends
102a and 102b by means of the thumb and index finger. In
the variant of Figure 2, the cross-section of the tube
102 is circular. The first portion 106b and the second
portion 106c of the housing 106 also present a shape that
is circularly cylindrical, but other shapes could be
used, providing they allow the head of the screw 110 to
pass, and providing the third portion 106d is
complementary in shape to the outside face of the bottom
portion of the stopper 104.

In the first variant embodiment of the package shown in Figure 1, said tube 102 has a single housing 106 opening out into its first end 102a.

The second variant embodiment of the package constituting the first aspect of the present invention and shown in Figures 2 and 2A is similar to the package described above with reference to Figure 1, except for the following points. The tube 102 of Figure 2 has two housings, i.e. a first housing 106 of the kind shown in Figure 1 opening out into the first end 102a of the tube 102, and also a second housing 108 for receiving a second screw 112 on its own.

Said second housing 108 presents an opening 108a opening out into said second end 102b. Second closure means constituted by another stopper 104 close said second housing in sealed manner and are suitable for being opened. Said second housing 108 extends in a longitudinal direction and presents a first portion 108b for receiving the shank of the second screw 112, and a second portion 108c, said second portion 108c being

larger than the first portion 108b and being suitable for receiving said head of the second screw 112 pressed thereagainst.

In addition, in order to remove the second screw 112 situated in the second housing 108, the package 100 of Figure 2 is turned upsidedown through 180°, so that the second end 102a then acts as a stand suitable for standing on a substantially horizontal plane (possibly via the intervening stopper 104), in particular in order to give access to the screw 112 situated in the second housing 108 via said opening 108a of said second housing 108 when said second closure means are open, said stand extending perpendicularly to the longitudinal direction. The first portion 108b for receiving the shank of the second screw 112 flares towards said opening 108a. addition, the second portion 108c presents at least a first fraction in the shape of a truncated cone, said head of the second screw coming to bear against said truncated cone shape. In particular, and as shown in Figures 2 and 2A, the entire second portion 108c of the second housing 108 is in the shape of a truncated cone. Provision can be made for the second portion 108b of the second housing 108 to be shorter than the first portion 106b of the first housing 106 in the event that the second housing 108 is for receiving a screw 112 that is shorter than the screw 110 housed in the first housing 106.

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When the screws 110 and 112 are being packaged in the tube 102, the previously-decontaminated screws 110 and 112 are placed in their respective housings 106 and 108, with the corresponding stoppers 104 being placed in the third portions 106d and 108d of the housings 106 and 108, after which the entire assembly is sterilized, preferably at low temperature under gamma rays. This ensures that the screws 110 and 112 remain sterile until the corresponding stopper 104 is removed.

The third variant embodiment of the package as shown in Figure 3 is similar to that described above with reference to the package of Figure 1, except for the following points. The tube 102 presents a circular section in its top portion that contains the first end However, in its bottom and middle portions, the section of the tube 102 is a circle that has been truncated by a straight line so as to define a plane side face or flat 102c that can make it easier to identify the position of the tube and that can make it easier to hold in the hand. The second portion 106c of the housing in this variant has a first fraction adjacent to the first portion 106b that is frustoconical in shape and a second fraction that is also frustoconical in shape and that is adjacent to the third portion 106d. It will be understood that the head of the screw can come to bear against the frustoconical first fraction of the second portion 106c that forms an angle relative to the main axis of longitudinal direction of the tube 102 (vertical in Figure 3) that is greater than the angle formed by the second fraction of the second portion 106c.

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The fourth variant embodiment of the package as shown in Figures 4a and 4b is similar to that described with reference to the package of Figure 1, except for the following points. In particular, unlike the tube 102 in the variants described above with reference to Figures 1 to 3, where the tube is solid except for the locations of the housing(s) 106 (and 108), the tube 102 in Figures 4A and 4B is hollow and the housing 106 is formed in a tubular part 114 that is contained at least in part inside said tube 102, with a closed space being formed between the tube 102 and the tubular part 114.

In particular, in the alternative shown in Figure 4A, the tubular part 114 is received almost entirely in the tube 102, with the opening 106a of the housing 106 defined by said tubular part 114 being

situated at almost the same height and very little above the first end 102a of the tube 102.

In the alternative shown in Figure 4B, the tubular part 114 is fully received in the tube 102, the opening 106a of the housing 106 defined by said tubular part 114 being situated at exactly the same height as the first end 102a of the tube 102 since the first end 102a of the tube 102 is in alignment with the top face of the second portion 106c of the housing defined in the opening 106a.

In both alternatives (Figures 4A and 4B), the tubular part 114 and the tube 102 are assembled together along their contact surfaces, e.g. by ultrasonic welding.

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In an alternative that is not shown, the tubular part 114 and the tube 102 are obtained in a single injection-molding step, with the second end 102b (constituting an end wall) then being a separate fitting: under such circumstances, the side wall and the first end 102a of the tube 102 and the tubular part 114 are made as a single part.

It should also be observed that the housing 106 defined by the tubular part 104 does not have a third portion, but only a first portion 106b for receiving the shank of a screw (which first portion is cylindrical or slightly tapering in shape towards the bottom), and a second portion 106c for receiving the head of the screw. This second portion is of the same shape as the second portion 106c of the housing 106 in the third variant embodiment shown in Figures 3 and 3A, i.e. it has a first frustoconical fraction with the bearing face 106f that flares widely, and a second frustoconical fraction that flares little, adjacent to the opening 106a.

Finally, it should be observed that the closure means are constituted by a film 116, e.g. a heat-sealable plastics film having the feature of being easy to remove, or possibly of being easily perforated by the tip 120a of the screwdriver 120 (see Figures 5 and 6) to give access to the head of the screw 110 whose bottom face is pressed

against the wall portion in the form of a truncated cone forming the first fraction of the second portion of the housing 106. This step of perforating the film and engaging the tip 120a of the screwdriver in the socket in the head of the screw 110 is shown in Figure 6.

Under such circumstances, it will be understood that said closure means comprise a preferably perforatable film 116 covering the opening 106a of the housing 106. It should be observed that the film 116 is thus preferably connected to the top end of the tubular part 114 so as to close the housing 106 in sealed manner. This connection may advantageously be implemented by ultrasonic welding, and in particular for the alternative shown in Figure 4b, the tubular part 114, the tube 102, and the film 116 can all be welded together simultaneously.

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In a first step of using the package 100 shown in Figure 4A or 4B, and as illustrated by Figure 5, the surgeon takes hold of the tube 102 firmly in one hand between the thumb and forefinger holding it so that its stand constituted by the second end 102s (at the bottom of Figure 5) is pressed against a support such as a table. Thereafter, in a second step of using the package of Figure 4, the surgeon takes a screwdriver 120 in the other hand and brings the tip 120a of the screwdriver blade so as to perforate the film 116 going downwards (given the slightly flaring shape of the second fraction of the second portion 106c), so as to penetrate into the socket situated in the head of the screw which remains firmly in place in its housing because the head of the screw is pressed against the first fraction of the second portion 106c of the housing (the bearing face 106f), with the resistance to the bearing force exerted by the tip coming from the first fraction of the second portion of the housing 106. Thereafter, in a third step (not shown), the surgeon takes the screw 110 out of the housing 106 merely moving the screwdriver 12 away from

the package 100. Thus, there is no contact between the screw and an outside element other than the tip of the screwdriver blade, thereby reducing the amount of handling (saving in time and improving accuracy) and reducing risks of contaminating the screw, which thus remains sterile on being taken out from the package 100.

In order to make it easier to take hold of the screw and avoid any interference with the film 116 during the second above-described step, it is possible to subdivide the action performed in this step by initially perforating and/or tearing the film 116, and then turning the tip 120a of the screwdriver blade so as to enlarge the hole through the film 116 prior to pushing the tip 120a further into the housing 106 in order to reach the head of the screw 110.

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Also preferably, provision is made for said tube 102 to carry at least one identification medium 122 bearing visible information about said screw 110 contained in the housing 106, which visible information may be constituted by a bar code. In Figure 6, it can be seen that such an identification medium 122 constituted by a label can advantageously be peeled off and then stuck into the file of the patient who is going to receive the screw 110 in question.

The second aspect of the invention is described below with reference to Figures 7 to 13 which show various embodiments thereof.

In the first embodiment of the second aspect shown in Figure 7, provision is made to place a plurality of packages 100 in accordance with the first aspect as described above in a plastics envelope 202 defining a closed compartment for each package, the whole constituting an assembly 200 for individually packaging and presenting each of the screws 110 in a series. The assembly 200 can be sterilized using gamma rays and can be made available in theater so as to enable the screws

110 to be taken one by one until all of the individual compartments have been opened.

In a second embodiment of the second aspect, as shown in Figure 8, there is shown an assembly 300 for packaging and individually presenting an osteosynthesis screw 110. The assembly 300 comprises a protective and packaging case 302.

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This protective and packaging case 302 is made of a plastics material in the form of a rigid portion 304 defining a space 306 containing a package 100, and a flexible portion 308 formed by a heat-sealable film closing said space 306 in sealed manner and suitable for being peeled off by hand.

Instead of or in addition to the label 122 placed on the outside face of the tube 102 of the package 100 (see Figure 6), another identification medium 322 is provided carrying information relating to the package 100 and the screw 110 it contains, in particular in the form of a bar code. In Figure 8, this other identification medium 322 is stuck on a location placed on the outside face of the rigid portion 304 of the protective and packaging case 302.

This assembly 300 can be packaged in a cardboard box together with other identical assemblies 300 placed one after another.

Reference is now made to Figure 9 showing a third embodiment of the second aspect of the present invention constituted by an assembly 400 for packaging and presenting an osteosynthesis equipment set comprising at least one osteosynthesis screw and at least one plate. The assembly 400 comprises a dish 402 (e.g. made of plastics, aluminum, or any other material), a heat-sealed film 408 closing the dish 402 in sealed manner, and cooperating therewith to define a storage space 406 in which one or more osteosynthesis plates (not shown) can be disposed. This storage space 406 also contains at least one individual package 100 for a screw

corresponding to the first aspect of the present invention.

Advantageously, this assembly 400 further comprises at least one insert placed in the storage space 406. In the variants shown in Figure 9, a single insert 410 is placed in the storage space 406 covering the entire bottom of the dish 402, with this insert that is made of plastics material being provided with at least one cavity 412 for receiving at least one osteosynthesis plate. The insert 410 shown in Figure 9 has a large L-shaped cavity 412 suitable for receiving side by side a plurality of osteosynthesis plates, together with one or more packages 100. The cavity 412 is provided with retaining means for positioning the osteosynthesis plate(s). More precisely, the retaining means are constituted by pegs 414 that can be received in the holes in the osteosynthesis plates.

Likewise, and advantageously, the insert 410 is also provided with at least one cell 416 receiving at least one osteosynthesis screw. In Figure 9, the insert 410 has six cells 416 each forming a hollow recess of shape corresponding substantially to the outside shape of an osteosynthesis screw. These cells 416 are particularly suitable for short screws unsuitable for placing in a package 100 suitable for a longer screw. These arrangements can thus be adapted as a function of the number of plates and the number of screws and of their dimensions so as to provide an assembly 400 in which the osteosynthesis equipment set constitutes a complete kit for a given surgical intervention.

Reference is now made to Figures 10 to 13 showing several alternatives for a fourth embodiment of the second aspect of the present invention constituted by an assembly 500 for packaging and presenting an osteosynthesis equipment set comprising at least one osteosynthesis screw and at least one plate. All of these assemblies 500 comprise a rigid support 502 e.g. made of molded or injection-molded plastics material,

defining a plurality of storage compartments, including at least one storage compartment of a first type 504 in which there is inserted a package 100 of the type constituting the first aspect of the present invention.

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Also, amongst the storage compartments in the rigid support 502, there can be found at least one storage compartment of the second type 506 for receiving at least one osteosynthesis plate 130 (see Figures 10 and 13). The rigid support 502 advantageously also contains at least one storage compartment of a third type 508 for receiving an osteosynthesis tool.

The rigid support 502 preferably has at least two compartments of the first type 504, each receiving a respective package 100 so that the assembly 500 makes available at least two osteosynthesis screws each housed in a package 100.

In the Figure 10 alternative of the fourth embodiment of the second aspect, the rigid support 502 has two storage compartments of the first type 504, each serving to receive one corresponding package 100, so that the rigid support 502 can receive six screws. addition, the rigid support 502 of Figure 10 has a storage compartment of a second type 506 suitable for receiving a plurality of osteosynthesis plates 130, and a storage compartment of the third type 508 of elongate shape suitable in particular for receiving a drill bit used by the surgeon in an initial stage prior to positioning and inserting the screw contained in the package 100. In Figure 10, the storage compartment of the third type 508 receives at least one screwdriver blade 120 together with a mandrel, the blade having its tip adapted to the shape of the socket in the head of each screw 110 in the packages 100.

In Figure 11, there can be seen another variant of an assembly 500 constituting the fourth embodiment of the second aspect of the present invention, the assembly comprising a rigid support 502 that is relatively flat and elongate, being provided with twelve storage compartments of the first type 504, one storage compartment of the second type 506 suitable for receiving a plurality of osteosynthesis plates, and a storage compartment of the third type 508 likewise suitable for receiving a drill bit and/or a screwdriver blade. The rigid support 502 of the assembly 500 shown in Figure 11 also includes at least one storage compartment of a fourth type 510 and at least one screwdriver portion disposed in the storage compartment of the fourth type 510 in the rigid support 502. As can be seen in Figure 11, the rigid support 502 of the assembly 500 has a single storage compartment of the fourth type 510 suitable for receiving all or part of a screwdriver (not shown).

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Consequently, provision can be made for the rigid support 502 to comprise in addition to storage compartments of the first type 504 and of the second type 506, at least one storage compartment of a third type 508 and at least one drill bit and/or screwdriver blade matching the screw contained in any one of the packages 100, and located in the storage compartment of the third type 508 of the rigid support 502.

Advantageously, and as can be seen in Figure 11, the storage compartment of the fourth type 510 is constituted by a cavity formed by two lobes corresponding to the outside shape of a screwdriver comprising a handle portion with a rear segment for placing in the palm of the hand and a front segment mounted to turn relative to the rear segment and suitable for carrying the screwdriver blade, with the front segment being manipulated by the tips of the fingers of the hand that is holding the rear segment in its palm. Since screwdrivers of this type are known, they are not described or shown in greater detail.

Figure 12 shows another alternative of the fourth embodiment of the second aspect constituted by an

assembly 500 with a rigid support 502 provided with six storage compartments of the first type 504, each housing a respective package 100, one storage compartment of the second type 506, suitable for housing a plurality of osteosynthesis plates 130, and two storage compartments of the third type 508, each suitable for housing one or more drill bits and/or screwdriver blades. In this alternative of the fourth embodiment of the second aspect of the present invention as shown in Figure 12 there is thus no storage compartment of the fourth type 510.

In Figure 13, there can be seen another alternative in the form of an assembly 500 similar to that of Figure 12 except that there is only one storage compartment of the third type 508.

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In a disposition that is advantageous and preferred, 15 but not essential, and as shown in Figures 11 and 13, the rigid support 502 constitutes a bottom portion as the assembly 500 also comprises a lid portion suitable for co-operating reversibly with the bottom portion 502 20 between an open position and a closed position. way, in the closed position, the lid portion 520 is suitable for retaining each of the packages 100 in the corresponding storage compartment of the first type 504 and for retaining the osteosynthesis plate(s) in 25 its(their) storage compartment of the second type 506. In the variants of Figures 11 and 12, the lid portion 520 is a part that is separate from the rigid support 502, whereas in the variant of Figure 13, the lid portion 520 is secured to the rigid support 502, forming therewith a pivoting hinge situated laterally along one of the edges 30 of the rigid support 502 and of the lid portion 520.

With the lid portion 520 of the variant shown in Figure 11, there are two regions of a first type 524 each constituted by a hollow zone positioned in register with a series of storage compartments of the first type 504 in order to house that portion of each package 100 that projects from the storage compartment of the first type

504. Also in the lid portion 520 of Figure 11, there is a region of a second type 526 that projects towards the storage compartment of the second type 506 in order to hold down the plates in the storage compartment of the second type 506. Similarly, the lid portion 520 of Figure 11 has a region of a fourth type 530 similarly shaped to the storage compartment of the fourth type 510 in Figure 11, i.e. having the outside shape of a screwdriver that is to be received and held in this location. Preferably, the rigid support 502 and the lid portion 520 are made of a plastics material and their edges have complementary shapes enabling these two portions to be snapped together.

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In the variant shown in Figure 12 where the lid portion 520 is likewise separate from the rigid support 502 forming the bottom portion, the lid portion 520 likewise has two regions of the first type 524 suitable for receiving the projecting portions of a row of packages 100 received individually in respective storage compartments of the first type 504 formed in the bottom portion of the rigid support 502. The lid portion in the variant of Figure 12 also has a region of the second type 526 formed by a projecting portion for inserting into the storage compartment of the second type 506 in order to hold down the plates 130. In this example, the edge of the bottom portion 502 and the edge of the lid portion 520 do not present any special arrangements for holding these two portions together, and they remain in position relative to each other because of the tight fit of the region of the first type 524 around the packages 100.

In the variant of Figure 13, the lid portion 520 presents a margin of a shape that is complementary to the shape of the margin of the bottom portion constituted by the rigid support 502. The lid portion 520 in Figure 13 also presents, on a face facing towards the bottom portion 502, a groove 524 (forming a region of the first type) that is substantially peripheral and in register

with the storage compartments of the first type 504, in order to be able to receive the projecting portions of the packages 100 individually received in the storage compartments of the first type 504. Thus, in the variant of Figure 13, the lid portion 520 likewise includes a region of the second type 526 projecting into the storage compartment of the second type 526 in order to hold down the plates 130 in the storage compartments of the second type 506.

In an advantageous disposition, the face of the lid portion 520 facing away from the bottom portion 502 presents a storage space 532 containing a dummy plate enclosed in sealed manner by a heat-sealable film 534 suitable for being removed manually.

15 More precisely, as can be seen in Figures 11 to 13, the region of the second type 526 in the lid portion that projects towards the bottom portion 502 presents a rear face in the form of a hollow defining the storage space This makes it possible to store a dummy plate, i.e. 20 an osteosynthesis plate that is not made of the biocompatible material of the osteosynthesis plate that is actually put into place, but that is made for example out of an aluminum alloy giving it a high degree of flexibility, enabling the surgeon to deform the dummy plate by hand while making initial positioning tests on 25 the site of the surgical intervention in order to verify that a plate of this shape and dimensions is indeed suitable for the surgery that is to be performed.

In another aspect of the present invention, as shown in Figures 14, the face of the lid portion 520 that faces away from said storage compartment 504, 506, 508 is provided with a label 522.

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This label 522 forms an identification medium carrying information relating to the osteosynthesis equipment set (screw 110 and plate 130), in particular information in the form of a bar code. This label 522 may naturally be placed somewhere other than on the

outside face of the packaging and presentation assembly 500.

More precisely, the label 522 has three portions 522a, 522b, and 522c, each of which carries the reference of the supplier that prepared and sterilized the osteosynthesis equipment set situated in the packaging and presentation assembly 500.

These portions 522a, 522b, and 522c carry various kinds of information including the serial number of the packaging and presentation assembly, the batch number, and the reference of each of the elements in the osteosynthesis equipment set (screw 110 and plate 130), information about the positions of each of the items in the osteosynthesis equipment set amongst the various housings (storage compartments of the first type 504, of the second type 506, or of the third type 508).

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Thus, after some of the elements making up the osteosynthesis equipment set received in the packaging and presentation assembly 500 have been used, it is possible to determine which elements are missing and to reconstitute the packaging and presentation assembly 500.

In addition, since the portions 522a, 522b, and 522c of the label 522 carry the same information, the portion 522a is kept for archive purposes, the portion 522b is stuck into the patient's file, and the portion 522c can be used for the surgical report.

In order to protect the packaging and presentation assembly 500 during transport and prior to using the osteosynthesis equipment it contains, the present invention also provides, in a third aspect, a protection assembly 600 which comprises not only the packaging and presentation assembly 500 as described above, but also:

· A dish 610 (see Figure 14) preferably made of transparent or translucent plastics material, the dish 610 defining a housing suitable for receiving the assembly 500, as can be seen in Figure 14. The dish 610 is generally rectangular in shape and likewise comprises

a bottom wall with a continuous side wall extending the margins of the bottom wall upwards, and a heat-sealable film 620 that closes the space defined by the dish 610 in sealed manner. The assembly 500 is preferably placed in the space defined by the dish 610, with the label 522 facing towards the heat-sealable film 620 so that the label 522 can be seen through the heat-sealable film. Ιt will thus be understood that this protective assembly 600 is characterized in that it comprises a packaging and presentation assembly 500, a protective dish 610 forming a container for said packaging and presentation assembly 500, and a heat-sealable film 620 suitable for being removed by hand and closing said dish 610 in sealed manner.

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15 · An outer protective and packaging case 630 optionally contains the dish (see Figure 15), this case likewise being made of plastics material that is preferably transparent or translucent, the case 630 also being formed by a bottom portion and a lid portion that 20 are movable relative to each other between an open position and a closed position, an outer label 640 preferably placed on the side wall of the case 630 providing means for visually observing the type of the osteosynthesis equipment set contained in the packaging 25 and presentation assembly 500 housed in the dish 610, itself placed in the bottom portion of the case 630. For this purpose, a color code carried by said external label 640 may designate a particular type of osteosynthesis equipment set.

It will thus be understood that the outer protective and packaging case 630 carries visual recognition means 640 pertaining to the type of osteosynthesis equipment set contained in said packaging and presentation assembly 500.

Similarly, it will be understood that the protective assembly 600 is characterized in that said outer protective and packaging case 630 comprises a bottom

portion and a lid portion that are movable relative to each other between an open position and a closed position, and in that said outer protective and packaging case 630 further comprises reversible closure means disposed on said bottom portion and on said lid portion that are suitable for co-operating in said closed position.

It should be observed that by having the label 640 situated on each of the protective and packaging cases 630 forming the outer envelope of the protective assembly 600, it is possible quickly and simply to determine the particular type of the osteosynthesis equipment set contained in each protective assembly 600 so as to select the case containing the packaging and presentation assembly 500 that contains the looked-for osteosynthesis equipment set.

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It should be observed that the items forming the osteosynthesis set shown in association with the above-described embodiment should not be restricted to equipment for performing osteotomy, in particular of the mandible, but could constitute equipment for other kinds of maxillofacial surgery, or more generally other kinds of osteosynthesis surgery.

Thus, more generally, the osteosynthesis equipment set may comprise one or more plates and/or one or more screws and/or one or more pins and/or one or more metal wires,